INTRODUCTION

Systemic opioids are commonly prescribed to manage postsurgical pain, but an overreliance on these drugs heightens the risk of adverse events. 

In the preclinical pig postoperative pain model, bupivacaine and meloxicam were found to have a synergistic effect when combined in the same extended-release (ER) formulation. This study assessed the clinical effectiveness of this combination in patients undergoing bunionectomy surgery.

OBJECTIVES

- Describe the study design and methods
- Compare pain intensity scores and pain relief
- Assess the tolerability of HTX-011

METHODS

Preclinical Methods

- Study Design (Figure 1)
- Animal Selection
- Surgical Incisions
- Postoperative Pain Assessment
- Study drug dosing
- Figure 2: Preclinical Pig Postoperative Pain Model Study Design

Clinical Subjects

- Clinical Study Design
- Clinical Methods
- Clinical Assessments
- Clinical Results
- Table 2: Key Clinical Characteristics
- Table 3: Key Criteria
- Figure 3: Time After Study Drug Administration, Mean Pain Intensity

CONCLUSIONS

- HTX-011 120 mg was generally well tolerated after bunionectomy and had an AE profile similar to that of saline placebo.
- HTX-011 significantly reduced mean pain intensity more than saline placebo, bupivacaine ER alone, or meloxicam ER alone.

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REFERENCES

- Miller's Anesthesia
- Adv Ther
- J Clin Pharmacol
- Pharmacother
- Clin Ther
- Improving Lives.